UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Prevention,
Pesticides and
Toxic Substances

August 6, 2002

SUBJECT: Carbaryl: Agency Response To Aventis Crop Science Error Correction Comments On Revised HED Risk Assessment and Supporting Documents, DP Barcode: D284591, PC Code: 056801

FROM: Jeffrey L. Dawson, Chemist/Risk Assessor
Reregistration Branch 1
Health Effects Division (7509C)

THRU: Whang Phang, PhD, Branch Senior Scientist
Reregistration Branch 1
Health Effects Division (7509C)

TO: Anthony Britten, Chemical Review Manager
Reregistration Branch 3
Special Review & Reregistration Division (7508C)

Attached is the Agency's response to 30 day error correction comments provided by Aventis Crop Science on the previous version of the human health effects risk assessment (D281420/ June 7, 2002). The registrant comments were included in the document entitled *Human Health Risk and Supporting Documents - Phase 1 Error Correction* (Date: July 12, 2002). The Agency's human health risk assessment was updated based on a number of the comments and re-issued on July 30, 2002 (D284580). The intent of this document is to illustrate how the comments were considered in the revisions to the risk assessment. The comments addressed the risk assessment, the product and residue chemistry chapter, and the occupational and residential risk assessment. Note that only the Agency risk assessment and not the supporting documents have been updated at this point. The Agency response is provided for each set of comments, respectively, in Sections 1, 2, and 3 of this document below.

Section 1: Human Health Risk Assessment

The Aventis Crop Science comments on the human health risk assessment are presented below as well as the Agency's responses to each.

Aventis Crop Science Comment 1:

EPA statement: The company name of the registrant is listed throughout the document as Aventis Corporation, Aventis Crop Sciences, Aventis Crop Science, and Aventis Crop Science Corporation.

Aventis' comment: Reference should be either to Aventis or Aventis CropScience.

Agency Response To Aventis Crop Science Comment 1:

The Agency has used Aventis Crop Science throughout the document.

Aventis Crop Science Comment 2:

1.0 Executive Summary

Dietary Risk Estimates (Page 7; Paragraph 3; Lines 4-6)

EPA statement: "In livestock commodities, carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, 5-methoxy-6-dydroxy carbaryl and all residues which can be hydrolyzed to carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, 5-methoxy-6-hydroxy carbaryl under acidic conditions …."

Aventis' comment: Add "and" before "5-methoxy-6-hydroxy carbaryl under acidic conditions ….".

Agency Response To Aventis Crop Science Comment 2:

The "and" has been added.

Aventis Crop Science Comment 3:

1.0 Executive Summary

Aggregate Risks and DWLOCs (Page 11; Paragraph 4; Lines 9-14)

EPA statement: "Additionally, acute dietary risks were also exceeded for infants and children (1 to 6 years old) at the 99.9th percentile when the Carbamate Market Basket Survey (CMBS) was not considered in the assessment (133% of aPAD). However, the risk picture could substantively change if residential risks are refined based on updated use information from the carbaryl use survey yet to be submitted to the Agency, and the Agency uses the CMBS data even with the caveats associated with that study."

Aventis' comment: This statement is inconsistent with information presented elsewhere in the HED Chapter. As written, the statement implies that the Agency has not yet approved the use of the CMBS data in the dietary risk assessment for carbaryl. However, EPA states in the Hazard Characterization section of the Executive Summary, page 6, paragraph 2, line 9, "Dietary exposures were calculated using FDA and PDP monitoring data, a carbamate market basket survey, and …" which indicates that the EPA approved the use of the CMBS data. In addition, it is stated on pages 8 and 31 (Footnotes) and page 37, first paragraph: "At the present time, information from the industry-sponsored Carbamate Market Basket Survey has been approved for use in dietary risk assessments with appropriate characterization of uncertainties associated with the conduct of the study. Hence, the use of these data in this assessment should be considered with associated caveats …"

Agency Response To Aventis Crop Science Comment 3:

The Agency has considered this and other comments related to the use and interpretation of the carbamate market basket survey results in a similar fashion. The intent of the Agency in any risk assessment is to present as broad a picture as possible to risk managers so they can make the most informed decisions possible given the resources available. This approach is very consistent with the Agency's available guidelines for exposure assessment and risk characterization.

In this case, both the CMBS and the PDP data (as well as the other data used in the Agency's dietary risk assessment) were considered to be acceptable for use in the risk assessment. However, both sources of data have associated uncertainties such as the rubbing issue in the CMBS. Additionally, it should be noted that if the Agency considers multiple sources of data acceptable for risk assessment, it does not mean that the

Agency would disregard other sources of information. This is particularly true when each one is considered to be of high quality yet still has uncertainties associated with its use. As such, the Agency has retained the comparative risk analyses based on the use, or not, of the CMBS in the recently revised risk assessment (D284580/July 30, 2002).

Aventis Crop Science Comment 4:

1.0 Executive Summary

Issues for Consideration (Page 16, Paragraph 1, Lines 19-26)

EPA statement: It should also be noted that Aventis Crop Sciences is in the process of conducting biological monitoring studies in residences where there have been carbaryl applications (sampling urine from children) and also for field workers during harvesting and hand thinning operations in apples and cherries. Preliminary results from these studies, based on personal communication with Aventis scientists (they have not been submitted to the Agency yet), indicate body burden levels similar to those calculated by the Agency for risk assessment purposes. For example, the turf risk assessments completed by the Agency are intended to provide upper percentile exposures. The data from the monitored children appear to indicate similar results a the upper percentiles.

Aventis' comment: This statement does not accurately reflect the true scope of the study and would be misleading. The comment would be more accurate as follows: "It should also be noted that Aventis CropScience has completed and is in the process of submitting to the Agency a biomonitoring study of individuals in residences following the application by a member of the household to the lawn and either the vegetable garden or ornamental flowers. A biomonitoring study of field workers during harvesting and hand thinning operations in apples and cherries will also be submitted to the Agency. Based on personal communication with Aventis scientists, preliminary results from the residential biomonitoring study indicate that the highest percentiles of the distribution of the younger children in the homes were similar to those predicted in the Agency's turf risk assessment for toddlers that are intended to represent the higher percentiles of the exposure distribution."

Agency Response To Aventis Crop Science Comment 4:

The Agency replaced the text in the revised assessment with that suggested by Aventis Crop Science.

Aventis Crop Science Comment 5:

4.0 Non-Occupational Risk Assessment and Characterization

4.1 Summary of Registered Uses (Page 28; Table 3: Technical and Manufacturing Carbaryl Products)

Aventis' comment: Carbaryl – Technical Products

- EPA Registration No. 45735-24 (99%), Carbaryl 99% Technical Grade Insecticide, Burlington Scientific Corporation, should be added to the list of registered carbaryl technical.
- EPA Registration No. 264-325 (97.5%), Aventis CropScience, should be included in the list of manufacturing-use products.

Carbaryl – Manufacturing-Use Products

- EPA Registration No. 5481-190 (46% FI), AMVAC Chemical corporation , is an active registration and should be added to the list of Manufacturing-Use Products. (It is listed in Table 1, page 2, of the Product and Residue Chemistry Chapters)
- EPA Registration No. 4816-270 (97.5%) is no longer active; it was transferred to EPA Registration No. 432-982 (97.5%), Aventis Environmental Science USA LP, on February 22, 2000.
- EPA Registration No. 4816-407 (1%) is no longer active; it was transferred to Reg. No. 432-1006 on February 22, 2000 and subsequently transferred to Reg. No. 73049-238, Valent Bioscience Corporation, on June 27, 2001 (neither 4816-407 or 432-1006 are active).
- As stated above, EPA Registration No. 264-325 (97.5%), Aventis CropScience, should be added to the list of manufacturing-use products.

Agency Response To Aventis Crop Science Comment 5:

The suggested modifications have been made to the risk assessment.

Aventis Crop Science Comment 6:

4.0 Non-Occupational Risk Assessment and Characterization

4.2 Dietary Risk Assessment (Page 31; Paragraph 1; Lines 3-5)

EPA statement: Carbaryl is used late in the season at maximal seasonal rates of 6-12 lb ai/acre. [Note: A Special Local Needs registration in California uses 16 lb ai/acre as a maximum rate on citrus.]

Aventis' comment: The **Section 3 registration** of carbaryl products cover the use on citrus at the rate of 5-16 lbs ai/acre ***in the state of California only***.

Agency Response To Aventis Crop Science Comment 6:

The suggested modifications have been made to the risk assessment.

Aventis Crop Science Comment 7:

4.0 Non-Occupational Risk Assessment and Characterization

4.3 Estimated Environmental Concentrations in Water

4.3.1 Environmental Fate Characteristics (Section 4.3.1, Pages 39-40)

Aventis' comment: The text in section 4.3.1 does not include the revisions that were made to the EFED draft Chapter and is inconsistent. For example:

- on Page 39, first paragraph of Section 4.3.1, first sentence "Carbaryl and its degradate 1-naphthol are fairly mobile but are not likely to persist or accumulate in the environment."
- on Page 40, Paragraph 1, last sentence "Carbaryl is mobile to very mobile in the environment (K_f = 1.7 to 3.2)."

The information in the EFED chapter has been revised to

- "Carbaryl is considered to be ***moderately mobile*** in soils" and the K_f range is 1.7 to 3.**5** (EFED Chapter, Page 20 – Table 3; Page 22 – Mobility).
- "… literature information suggest that it [1-naphthol] is ***less persistent and less mobile*** than parent carbaryl."(EFED Chapter, Page 26, 1-Naphthol Fate and Transport).

Agency Response To Aventis Crop Science Comment 7:

The suggested modifications have been made to the risk assessment.

Aventis Crop Science Comment 8:

4.0 Non-Occupational Risk Assessment and Characterization

4.3 Estimated Environmental Concentrations in Water
4.3.1 Environmental Fate Characteristics (Section 4.3.1, Paragraphs 2 and 3 (pages 39-40))

EPA statement: In these 2 paragraphs, the chemical name for the major carbaryl degradation product is typed as "1-napthol".

Aventis' comment: Correct spelling is "1-nap**h**thol".

Agency Response To Aventis Crop Science Comment 8:

The suggested modifications have been made to the risk assessment.

Aventis Crop Science Comment 9:

4.0 Non-Occupational Risk Assessment and Characterization

4.4 Residential Risk Assessment
4.4.2.2 Residential Handler Cancer Risks (Page 52; Paragraph 1; Lines 11-12)

EPA statement: "…[Note: Scenarios where risks are still of concern (i.e., $<1x10^{-6}$) are highlighted in the table.].

Aventis' comment: (i.e., **"<"**$1x10^{-6}$) should be corrected to (i.e., **">"**$1x10^{-6}$).

Agency Response To Aventis Crop Science Comment 9:

The suggested modifications have been made to the risk assessment.

Aventis Crop Science Comment 10:

4.0 Non-Occupational Risk Assessment and Characterization

4.4 Residential Risk Assessment
4.4.3 Residential Postapplication Risk Assessment (Page 59; Paragraph 1; Lines 4-6)

EPA statement: These levels were The Agency instead considers them a qualitative indicator that exposures in the general population are likely to occur.

Aventis' comment: Words are missing from the first part of the sentence.

Agency Response To Aventis Crop Science Comment 10:

The suggested modifications have been made to the risk assessment.

Aventis Crop Science Comment 11:

4.0 Non-Occupational Risk Assessment and Characterization

4.4 Residential Risk Assessment
4.4.3 Residential Postapplication Risk Assessment (Page: 59 Paragraph: 2 Lines: 1-6)

EPA statement: Aventis Crop Science is in the process of conducting a biomonitoring study with children who live in households where carbaryl has been used. Based on discussions with Aventis, the preliminary results indicate that levels at the highest percentiles of the distribution are similar to those predicted in the Agency's turf risk assessment for toddlers which are intended to represent the higher percentiles of the exposure distribution. A more detailed analysis will be completed upon submission

Aventis' comment: The statement does not accurately reflect the true scope of the study and would be misleading. The comment would be more accurate as follows:

Aventis CropScience has completed and is in the process of submitting to the Agency a biomonitoring study of individuals in residences following the application by a member of the household to the lawn and either the vegetable garden or ornamental flowers. Based on discussions with Aventis, preliminary results indicate that the highest percentiles of the distribution of the younger children in the homes were similar to those predicted in the Agency's turf risk assessment for toddlers that are intended to represent the higher percentiles of the exposure distribution. A more detailed analysis will be completed upon submission.

Agency Response To Aventis Crop Science Comment 11

The suggested modifications have been made to the risk assessment.

Aventis Crop Science Comment 12:

5.0 Aggregate Risk Assessments and Risk Characterization

5.1 Calculation of Aggregate Risks and DWLOCs (Page 72; Paragraph 2; Lines 6-11)

EPA statement: "Additionally, acute dietary risks were also exceeded for infants and children (1 to 6 years old) at the 99.9th percentile when the Carbamate Market Basket Survey (CMBS) was not considered in the assessment. However, the risk picture could substantively change if residential risks are refined based on updated use information from the carbaryl use survey yet to be submitted to the Agency ***and the Agency chooses to regulate using the results of the CMBS***."

Aventis' comment: This statement is inconsistent with information presented elsewhere in the HED Chapter. As written, the statement implies that the Agency has not yet approved the use of the CMBS data in the dietary risk assessment for carbaryl. However, EPA states in the Hazard Characterization section of the Executive Summary, page 6, paragraph 2, line 9, "Dietary exposures were calculated using FDA and PDP monitoring data, a carbamate market basket survey, and …" which indicates that the EPA approved the use of the CMBS data. In addition, it is stated on pages 8 and 31 (Footnotes) and page 37, first paragraph: "At the present time, information from the industry-sponsored Carbamate Market Basket Survey has been approved for use in dietary risk assessments with appropriate characterization of uncertainties associated with the conduct of the study. Hence, the use of these data in this assessment should be considered with associated caveats …"

Agency Response To Aventis Crop Science Comment 12:

Please refer to the Agency response to Aventis Crop Science comment 3 above.

Aventis Crop Science Comment 13:

5.0 Aggregate Risk Assessments and Risk Characterization

5.7 Summary of Aggregate Risks (Page 76; Paragraph 2; Lines 3-4 continued on page 77)

EPA statement: "Additionally, acute dietary risks were also exceeded for infants and children (1 to 6 years old) at the 99.9th percentile when the Carbamate Market Basket Survey (CMBS) was not considered in the assessment. However, the risk picture

could substantively change if residential risks are refined based on updated use information from the carbaryl use survey yet to be submitted to the Agency ***and the Agency chooses to regulate using the results of the CMBS***."

Aventis' comment: This statement is inconsistent with information presented elsewhere in the HED Chapter. As written, the statement implies that the Agency has not yet approved the use of the CMBS data in the dietary risk assessment for carbaryl. However, EPA states in the Hazard Characterization section of the Executive Summary, page 6, paragraph 2, line 9, "Dietary exposures were calculated using FDA and PDP monitoring data, a carbamate market basket survey, and …" which indicates that the EPA approved the use of the CMBS data. In addition, it is stated on pages 8 and 31 (Footnotes) and page 37, first paragraph: "At the present time, information from the industry-sponsored Carbamate Market Basket Survey has been approved for use in dietary risk assessments with appropriate characterization of uncertainties associated with the conduct of the study. Hence, the use of these data in this assessment should be considered with associated caveats …"

Agency Response To Aventis Crop Science Comment 13:

Please refer to the Agency response to Aventis Crop Science comment 3 above.

Aventis Crop Science Comment 14:

7.1 Occupational Handler Risk Assessment (Page: 83; Paragraph 5; Lines 9-10 and Footnote)

EPA statement: There are no data compensation issues with any of these data. [11].

(Footnote) [11] Non-ORETF data included in MRIDs 451672-01 and 452507-01 were from studies submitted by Aventis CropScience. The propoxur trigger sprayer study has a signed PHED data waiver but has not been included into PHED.

Aventis' comment: Aventis concurs that there are no data compensation issues. However, the rationale presented for the propoxur trigger sprayer study is not accurate. The PHED data waiver is applicable only when the data are in PHED and not when cited outside of PHED. The propoxur study does not trigger data compensation because the study is the property of Bayer CropScience which has recently acquired Aventis CropScience.

Agency Response To Aventis Crop Science Comment 14:

The suggested modifications have been made to the risk assessment.

Section 2: Product and Residue Chemistry

This section addresses the comments received from Aventis Crop Science pertaining to the product and residue chemistry supporting document (D283328). This document has not been altered at this point to reflect the changes suggested by the registrant, Aventis Crop Sciences. Rather, specific changes which could impact the results of the risk assessment were considered and the appropriate modifications were made to the risk assessment. The Agency response to comments provided by Aventis will serve as errata to the product and residue chemistry chapter (D283328).

Aventis Crop Science Comment 15:

General several References Throughout the Document

EPA statement: The company name of the registrant is listed throughout the document as Aventis Ag Company.

Aventis' comment:
Reference should be to Aventis CropScience.

[Note: This issue was repeated in the Aventis Crop Science comments pertaining to the product and residue chemistry chapters. It is only addressed here.]

Agency Response To Aventis Crop Science Comment 15:

The suggested modifications will be made to the product and residue chemistry chapter (D283328) if and when the document is reissued. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect the suggested change.

Aventis Crop Science Comment 16:

Product Chemistry Chapter/Manufacturing-Use Products (Page 2; Table 1 – Registered Carbaryl Manufacturing-Use Products)

Aventis' comment:

- EPA Registration No. 45735-24 (99%), Carbaryl 99% Technical Grade Insecticide, Burlington Scientific Corporation, should be added to the list of registered carbaryl technical.

- EPA Registration No. 4816-270 (97.5%) is no longer active; it was transferred to EPA Registration No. 432-982 (97.5%), Aventis Environmental Science USA LP, on February 22, 2000.

- EPA Registration No. 4816-407 (1%) is no longer active; it was transferred to Reg. No. 432-1006 on February 22, 2000 and subsequently transferred to Reg. No. 73049-238, Valent Bioscience Corporation, on June 27, 2001 (neither 4816-407 or 432-1006 are active).

- The name of the registrant for EPA Registration No. 769-971 is Value Gardens Supply, LLC.

Corresponding corrections should be made to the Product Chemistry Section of the Memorandum for this Chapter and in other sections of the Product Chemistry Chapter of the Reregistration Eligibility Decision (RED) Document.

Agency Response To Aventis Crop Science Comment 16:

The suggested modifications will be made to the product and residue chemistry chapter (D283328) if and when the document is reissued. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect the suggested change.

Aventis Crop Science Comment 17:

Regulatory Background (Page 2: Paragraph 2: Line 5)

EPA statement: "... but should not delay on the reregistration eligibility decisions for carbaryl."

Aventis' comment: Remove "on" from the sentence, "... but should ~~not~~ delay on the reregistration..."

Agency Response To Aventis Crop Science Comment 17:

The Agency is unclear about this comment but will review the affected text and make appropriate changes.

Aventis Crop Science Comment 18:

Summary of Science Findings GLN 860.1200: Directions for Use (Page 3: Table A1. Carbaryl EPs with Food/Feed Uses Registered to Aventis Ag Company)

EPA statement: EPA Registration No. 264-430 is listed on this table.

Aventis' comment: The registration of Sevin Brand Granular Carbaryl Insecticide For Outdoor Home Use, EPA Registration No. 264-430, was transferred to Aventis Environmental Science, EPA Registration No. 432-885 on February 9, 2000.

Agency Response To Aventis Crop Science Comment 18:

The appropriate changes to the product and residue chemistry chapter will be made after verification by the chemical review manager. There is no anticipated impact on the results of the risk assessment.

Aventis Crop Science Comment 19:

GLN 860.1380: Storage Stability Data - Plants (page 6: Paragraph 1; Lines 2-3)

EPA statement: Additional data are required depicting the storage stability of carbaryl *per se* in an oilseed, processed commodities of an oily crop, and a **dried fruit stored up to 10 months.**

Aventis' comment: Inconsistencies are noted between the information presented in the section "Summary of Science Findings" and Table B. Residue Chemistry Science Assessments for Reregistration of Carbaryl (page 63)

Paragraph 1 of the "GLN 860.1380: Storage Stability Data - Plants" section indicates the need for storage stability data for dried fruit (in addition to other items). Table B data requirements (page 63 along with footnote #14 on page 73) does not request storage stability data for dried fruit; neither does the 4th paragraph on page 6 (GLN 860.1380).

Agency Response To Aventis Crop Science Comment 19:

The appropriate modifications will be made to the product and residue chemistry chapter (D283328) if and when the document is reissued. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect appropriate changes.

Aventis Crop Science Comment 20:

GLN 860.1500: Crop Field Trials (Page 7, paragraph 5)

EPA statement: "In addition, conclusions regarding the adequacy of the data for alfalfa, **apples**, potatoes... are contingent upon receipt and acceptance of adequate supporting storage stability data."

Aventis' comment: The statement is inconsistent with information elsewhere in the document. There is no requirement for storage stability data on apples in the "GLN 860.1380: Storage Stability Data - Plants" section (page 6) nor in Table B (page 63 along with footnote #14 on pate 73).

Agency Response To Aventis Crop Science Comment 20:

The appropriate modifications will be made to the product and residue chemistry chapter (D283328) if and when the document is reissued. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect appropriate changes.

Aventis Crop Science Comment 21:

GLN 860.1500: Crop Field Trials (Page 8, paragraph 14, Line 4)

EPA statement: "However, additional residue data are required if the registrant seeks tolerances for residues in/on succulent, shelled pea and bean commodities." (Also stated in the Memorandum on page 3, paragraph 3).

Aventis' comment: This statement is in contradiction with paragraph 6 of this section: "... adequate magnitude of the residue data are available on the following crops: ... beans (dried and succulent), ... peas (dried and succulent..." and Table B requirements for crop field trials (page 65). Also, MRID 43984701 (succulent bean) and MRID 43703102 (fresh pea) were found to be acceptable.

Agency Response To Aventis Crop Science Comment 21:

The appropriate modifications will be made to the product and residue chemistry chapter (D283328) if and when the document is reissued after verification by the chemical review manager. There is no anticipated impact on the results of the risk assessment.

Aventis Crop Science Comment 22:

GLN 860.1520: Processed Food/Feed (page 9, paragraph 1, lines 4-6)

EPA statement: Based on the available processing studies, tolerances are required for residues in citrus fruit oil, **raisins, wet apple pomace**, and rice hulls only.

Aventis' comment: EPA requests processed commodity tolerances for (among other commodities) wet apple pomace and raisins (see also Table C, page 85). Calculations according to the 860.1520 Guidelines indicate that processed commodity tolerances are not needed for these commodities. The Agency's statement appears to be the result of a mathematical or computational type error since the 860.1520 Guidelines are rather clear on determination of need for processed commodity tolerances.

Agency Response To Aventis Crop Science Comment 22:

The appropriate modifications will be made to the product and residue chemistry chapter (D283328) if and when the document is reissued. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect appropriate changes.

Aventis Crop Science Comment 23:

GLN 860.1480: Meat, Milk, Poultry, Eggs (page 11: paragraph 3, line 5)

EPA statement: "The calculation of the maximum dietary is tentative..."

Aventis' comment: Add the word "burden" to the statement "The calculation of the maximum dietary **(burden)** is tentative...".

Agency Response To Aventis Crop Science Comment 23:

The Agency will add the word "burden" to the text of the document.

Aventis Crop Science Comment 24:

GLN 860.1480: Meat, Milk, Poultry, Eggs (page 11: paragraph 4, lines 1-2)

EPA statement: "... tolerances for residues of carbaryl ***per se*** in livestock (excluding swine) commodities should be reassessed..."

Aventis' comment: The tolerance expression in GLN 860.1480 should be modified to agree with the one in GLN 860.1300 (page 4): "... tolerances for ruminant meat and milk should be expressed as residues of free and conjugated carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, and 5-methoxy-6-hydroxy carbaryl."

Agency Response To Aventis Crop Science Comment 24:

The appropriate modifications will be made to the product and residue chemistry chapter (D283328) if and when the document is reissued. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect appropriate changes.

Aventis Crop Science Comment 25:

Tolerance Reassessment Summary, Table C. Tolerance Reassessment Summary For Carbaryl, Tolerance Listed Under 40 CFR §180.169 (a), page 79
Aventis' comment: Under the commodity "Corn, forage", Comments on "Corn, sweet, forage": should read "Residue data indicate that the tolerance for sweet corn forage should be increased." (i.e., replace "field" with "sweet" in the sentence).

Agency Response To Aventis Crop Science Comment 25:

The appropriate modifications will be made to the product and residue chemistry chapter (D283328) if and when the document is reissued. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect appropriate changes.

Section 3: Occupational & Residential Exposure

This section addresses the comments received from Aventis Crop Science pertaining to the occupational and residential exposure supporting document (D281418). This document has not been altered at this point to reflect the changes suggested by the registrant, Aventis Crop Sciences. Rather, specific changes which could impact the results of the risk assessment were considered and the appropriate modifications were made to the risk assessment. The Agency response to comments provided by Aventis will serve as errata to the occupational and residential exposure/risk assessment chapter (D281418).

Aventis Crop Science Comment 26:

General, Several References Throughout the Document

EPA statement: The company name of the registrant is listed throughout the document as Aventis Corporation and Aventis Crop Science.

Aventis' comment: Reference should either to Aventis or Aventis CropScience.

Agency Response To Aventis Crop Science Comment 26:

The suggested modifications will be made to the occupational and residential exposure chapter (D281418) if and when the document is reissued. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect the suggested change.

Aventis Crop Science Comment 27:

Executive Summary (Page 10, paragraph: 3, Lines 16-20)

EPA comment: [Note: The Aventis Corporation is in the process of conducting a biomonitoring study with children who live in households where carbaryl has been used. Preliminary results indicate that levels at the highest percentiles of the distribution were similar to those predicted in the Agency's turf risk assessment for toddlers which are intended to represent the higher percentiles of the exposure distribution. A more detailed analysis will be completed upon submission.]

Aventis's response: The statement does not accurately reflect the true scope of the study and would be misleading. The comment would be more accurate as follows:

> Aventis Crop Science has completed and is in the process of submitting to the Agency a biomonitoring study of individuals in residences following the application by a member of the household to the lawn and either the vegetable garden or ornamental

flowers. Preliminary results indicate that the highest percentiles of the distribution of the younger children in the homes were similar to those predicted in the Agency's turf risk assessment for toddlers that are intended to represent the higher percentiles of the exposure distribution. A more detailed analysis will be completed upon submission.

Agency Response To Aventis Crop Science Comment 27:

The suggested modifications will be made to the occupational and residential exposure chapter (D281418) if and when the document is reissued. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect the suggested change.

Aventis Crop Science Comment 28:

1.0 Occupational and Residential Exposure/Risk Assessment

1.5 Summary of Use Patterns and Formulations

1.5.1 End-Use Products (page 15, table 2)

Aventis' comment:

Carbaryl – Technical Products

- EPA Registration No. 45735-24 (99%), Carbaryl 99% Technical Grade Insecticide, Burlington Scientific Corporation, should be added to the list of registered carbaryl technical.
- EPA Registration No. 264-325 (97.5%), Aventis CropScience, should be included in the list of manufacturing-use products.

Carbaryl – Manufacturing-Use Products

- EPA Registration No. 5481-190 (46% FI), AMVAC Chemical corporation , is an active registration and should be added to the list of Manufacturing-Use Products. (It is listed in Table 1, page 2, of the Product and Residue Chemistry Chapters)
- EPA Registration No. 4816-270 (97.5%) is no longer active; it was transferred to EPA Registration No. 432-982 (97.5%), Aventis Environmental Science USA LP, on February 22, 2000.
- EPA Registration No. 4816-407 (1%) is no longer active; it was transferred to Reg. No. 432-1006 on February 22, 2000 and subsequently transferred to Reg. No. 73049-238, Valent Bioscience Corporation, on June 27, 2001 (neither 4816-407 or 432-1006 are active).
- As stated above, EPA Registration No. 264-325 (97.5%), Aventis CropScience, should be added to the list of manufacturing-use products.

Agency Response To Aventis Crop Science Comment 28:

The suggested modifications will be made to the occupational and residential exposure chapter (D281418) if and when the document is reissued pending verification by the chemical review manager. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect the suggested change. [Note: This comment was also addressed above in the risk assessment section.]

Aventis Crop Science Comment 29:

1.5.3 Registered Use Categories and Sites (page 20, animal uses)

EPA statement:

Poultry (Chickens, ducks, geese, game birds, turkeys)
Livestock (cattle, sheep, horses, etc.)

Aventis' comment: Both uses should be removed from the list of registered uses. Aventis voluntarily requested the deletion of the use on poultry. A Federal Register Notice dated October 24, 2001 announced receipt by the Agency of an application from Aventis Crop Science to delete this use. The use on livestock (cattle, sheep, horses, etc.) is no longer registered. Aventis will not support the reregistration of this use.

Agency Response To Aventis Crop Science Comment 29:

The suggested modifications will be made to the occupational and residential exposure chapter (D281418) if and when the document is reissued once the suggested changes are verified by the chemical review manager. It should be noted that an August 1, 2002 review of the Agency's REFs system still had active registrations listed for both poultry and unspecified livestock and horses. There were some registrations for cattle that were listed as inactive.

Aventis Crop Science Comment 30:

1.5.3 Registered Use Categories and Sites (page 21, aquatic food crop)

EPA statement: Aquatic sites - commercial fishery water systems

Aventis' comment: This use is not listed on Aventis Carbaryl product labels.

Agency Response To Aventis Crop Science Comment 30:

The use likely attributed to this site is from EPA Reg. No. 264-316, SLN WA-900013 which is for Sevin Brand 80S Carbaryl Insecticide For Control Of Ghost and Mud Shrimp in Oyster Beds in Washington state.

Aventis Crop Science Comment 31:

1.5.3 Registered Use Categories and Sites (page 21, aquatic non-food industrial)

EPA statement: Aquatic sites - drainage systems

Aventis' comment: This use is not listed on Aventis carbaryl products labels.

Agency Response To Aventis Crop Science Comment 31:

The suggested modifications will be made to the occupational and residential exposure chapter (D281418) if and when the document is reissued once the suggested changes are verified by the chemical review manager and another review of available labels is completed. It should be noted that an August 1, 2002 review of the Agency's REFs system still had an active registration for this site.

Aventis Crop Science Comment 32:

2.0 Occupational Exposures and Risks

2.1 Occupational Handler Exposures and Risks

2.1.2 Data and Assumptions For Handler Exposure Scenarios (page 36, paragraph 1, lines 1 - 4)

EPA statement: There are no data compensation issues associated with the use of non-ORETF data... and the propoxur trigger sprayer study has a signed PHED data waiver but just has not been included into PHED at this time.

Aventis' response: Aventis concurs that there are no data compensation issues. However, the rationale for the propoxur trigger sprayer study is not correct. The PHED data waiver is applicable only when the data are in PHED and not when cited outside of PHED. The propoxur study does not trigger data compensation because the study is the property of Bayer Crop Science which has acquired Aventis Crop Science.

Agency Response To Aventis Crop Science Comment 32:

The suggested modifications will be made to the occupational and residential exposure chapter (D281418) if and when the document is reissued. Otherwise the Agency acknowledges this comment and has altered the overall risk assessment document to reflect the suggested change. [Note: This comment was also addressed above in the risk assessment section.]

Aventis Crop Science Comment 33:

3.0 Residential and Other Non-Occupational Exposures and Risks

3.1 Residential Handler Exposures and Risks

3.1.2 Data and Assumptions For Handler Exposure Scenarios (page 99, paragraph:2, line 9)

EPA statement: "Longitudinal data, however, were not available to establish that such populations definitively exist."

Aventis' comment: The following should be added after this sentence to accurately reflect the submission of Residential Exposure Joint Venture data for carbaryl that covers use patterns by the same individuals between May and August.

> "Note: Aventis has recently submitted an analysis of longitudinal residential use patterns of carbaryl that monitored the use of carbaryl within several thousand households between the months of May through August."

Agency Response To Aventis Crop Science Comment 33:

At the time the occupational and residential exposure/risk assessment was completed, the Residential Exposure Joint Venture data for carbaryl had not yet been submitted by Aventis Crop Science. The Agency will review this information, both in the context of a deterministic and a probabilistic risk assessment strategy. Results from this study will be incorporated into any revisions to the human health risk assessment and the occupational and residential exposure/risk assessment documents as appropriate.

Aventis Crop Science Comment 34:

3.0 Residential and Other Non-Occupational Exposures and Risks

3.1 Residential Handler Exposures and Risks

3.1.2 Data and Assumptions For Handler Exposure Scenarios (pages 104-105, Discussion of OMA004)

EPA statement: The discussion presents exposure data for Dial-type (DTS) Homeowner Hose-End sprayers and Ready-to-Use Sprayers. However, Table 23 and subsequent risk and exposure tables only present exposure estimates based on the DTS sprayer.

Aventis' response: The RTU sprayer is an important component of the carbaryl market and was developed as an exposure mitigation product that eliminates the homeowner's need to pour concentrated formulations of carbaryl. The OMA004 study demonstrated significant reductions in the exposure to homeowners and the presentation of the resultant RTU hose-end sprayer data, exposure, and risk is essential to the residential handler section.

Agency Response To Aventis Crop Science Comment 34:

The Agency did not include a quantitative analysis based on the ready-to-use (no mixing/loading) product because it is unclear if the packaging used in the study is similar to the containers used for carbaryl and it is also not clear what percentage of the market for carbaryl is accounted for by the no-mix containers. The Agency calculated risk estimates based solely on the hose-end sprayer data that required users to add concentrated formulation to the device. Both sets of information will be considered in any risk management decision. The Agency used the following unit exposures in its assessment (i.e., the open mixing data from ORETF Study OMA004):

- Dermal geo. mean for a person wearing shorts and a short-sleeved shirt: 11 mg/lb ai
- Inhalation geo. mean for a person not wearing a respirator: 16 µg/lb ai

[Dermal exposure drives the overall risk estimate so any change in dermal exposure would clearly and proportionally alter the overall risk estimate. The total MOE (includes both dermal and inhalation exposures) for broadcast applications to lawns is 25 while the MOE for spot treatments is 495 (Agency target is 100).]

The unit exposure values from ORETF Study OMA004 where no mixing dial type sprayers were used are as follows:

- Dermal geo. mean for a person wearing shorts and a short-sleeved shirt: 2.6 mg/lb ai
- Inhalation geo. mean for a person not wearing a respirator: 11 µg/lb ai

If the MOE for broadcast applications is adjusted for changes in the dermal exposure estimate, then the MOE would be ~106 (25*11/2.6) which exceeds Agency targets. This information will be considered in the risk management decisions as well as the feasability of using the no-mix containers in 100 percent of the carbaryl market.

Aventis Crop Science Comment 35:

3.2 Residential Postapplication Exposures and Risks

3.2.2 Data and Assumptions For Residential Postapplication Exposure Scenarios (Page: 122 Paragraph: 5 Lines: 1-6)

EPA statement: Aventis Crop Science is in the process of conducting a biomonitoring study with children who live in households where carbaryl has been used. Preliminary results indicate that levels at the highest percentiles of the distribution were similar to those predicted in the Agency's turf risk assessment for toddlers which are intended to represent the higher percentiles of the exposure distribution. A more detailed analysis will be completed upon submission

Aventis' comment: The statement does not accurately reflect the true scope of the study and would be misleading. The comment would be more accurate as follows:

Aventis CropScience has completed and is in the process of submitting to the Agency a biomonitoring study of individuals in residences following the application by a member of the household to the lawn and either the vegetable garden or ornamental flowers. Preliminary results indicate that the highest percentiles of the distribution of the younger children in the homes were similar to those predicted in the Agency's turf risk assessment for toddlers that are intended to represent the higher percentiles of the exposure distribution. A more detailed analysis will be completed upon submission.

Agency Response To Aventis Crop Science Comment 35:

The suggested modifications have been made to the risk assessment.

Aventis Crop Science Comment 36:

3.2.4 Residential Postapplication Exposure and Noncancer Risk Estimates (page 132 and 135, Tables 26 and 28)

EPA comment: The residential turf (lawncare) scenario does not differentiate between liquid spray and granular formulation applications.

Aventis' response: There is significant differences in the postapplication exposure potential following a liquid spray application compared to a granular application. ORETF data submitted to the Agency indicate that transferable residues following a granular application are about 10 times less than a liquid spray application . In addition, ORETF has recently conducted a large postapplication exposure study in Moses Lake, Washington that will provide both adult Jazzercise and Children's Activity Pattern (CHAPs) transfer coefficients. Although the Moses Lake data have not yet been submitted, the conduct of the study should be referenced and the tables should differentiate between the very different liquid spray and granular lawn postapplication exposure scenarios.

Agency Response To Aventis Crop Science Comment 36:

The Agency acknowledges this comment and will incorporate data from this study as appropriate in the risk assessment and risk management process. It should be noted that even there appears to be differences between TTR (turf transferable residues) levels after liquid or granular formulation applications, Aventis Crop Science only completed a TTR study using a liquid formulation of carbaryl.